

§71.4

deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug, notification to the petitioner will be made in accordance with §70.10(b)(3) of this chapter.

(b) The Commissioner will cause to be published in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

[42 FR 15639, Mar. 22, 1977, as amended at 64 FR 400, Jan. 5, 1999]

§71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 721(d)(1) of the act shall be moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the informa-

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tion and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) *Extension of time for studying petitions.* If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. If clinical investigations involving human subjects are involved, additional information or data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §56.104 or §56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 71.20 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985]

§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved

with the report, such as a physician or hospital or other institution.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All records showing the Food and Drug Administration's testing of or action on a particular lot of a certifiable color additive.

(b) The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(c) All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure in accordance with the provisions of part 20 of this chapter when the color additive regulation is published in the FEDERAL REGISTER.

(d) For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies